SUMMARY OF SAFETY & EFFECTIVENESS

OCT 2 3 2003 K032996

Elekta Limited hereby provide the following material summarising safety and effectiveness information for the Elekta Synergy™ System. This information is summarised as follows: -

1. The Elekta Synergy™ System is an enhancement to the previously reported Precise Treatment Systems Digital Accelerator (formally designated the SL/SL*i* Series, D.C. K963624) and its commercially available options.

   These devices have an established and proven track record for safety. The primary reason for the introduction of this product is to improve information available to allow the set up of the patient position as part of the treatment process. The Elekta Synergy™ System does not raise additional types of safety or effectiveness considerations.

2. It is our opinion that the Elekta Synergy™ System does not have technological characteristics that raise additional types of safety or effectiveness questions, and that we consider it an enhancement to the previously cleared devices within the Elekta product range.

3. The accompanying documents provided for the user contain comprehensive information to ensure safe and effective use. Past experience with substantially equivalent predicate devices has shown our device to be safe and effective when used as directed by the accompanying documents provided for the user.

4. The components of the Elekta Synergy™ System are subject to compliance testing as defined in the internationally recognised safety standards IEC 60601-1 and IEC 60601-2-1.

5. The components of the Elekta Synergy™ System are designed to bear the CE mark affirming compliance with all relevant European Directives in force, in particular the European Medical Device Directive. As a result of this, products may be sold freely without restriction throughout the entire European Union.

6. The Elekta Limited Quality Management System has been established to satisfy the requirements of ISO 9001, ISO 13485, the Medical Device Directive 93/42/EEC Annex II and US 21 CFR 820. Elekta Limited has developed the Elekta Synergy™ System using an established and documented Quality Management System.

SUMMARY OF SAFETY & EFFECTIVENESS

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7. Elekta Limited is a registered medical device manufacturer of assessed capability against the requirements of ISO 9001, ISO 13485 and the Medical Device Directive 93/42/EEC Annex II.

8. In accordance with the above requirements all parts of the Quality System are subject to periodic and systematic internal Quality Audits. These audits are performed by trained personnel not having direct responsibilities in the functions being audited.

9. The quality system is subject to regular, planned and documented GMP audits conducted by external auditors from SGS Yarsley (UK Notified Body) and the FDA.

10. Elekta Limited has conducted hazard analysis on the elements of the Elekta Synergy™ System and has concluded that it does not introduce hazards that raise new types of safety or effectiveness considerations. After considering the Guidance for the Content of Pre-Market Notification Submissions of Medical Devices Containing Software Elekta Limited has concluded the level of concern appropriate to the device is "Major".

Signature ..... Date 12 SEP 2003

Vice President Research & Development

Signature ..... Date 12 Sept 2003

Director Product Management

Signature ..... Date 12/09/03

Regulatory Affairs Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 3 2003

Elekta Oncology Systems, Ltd.
% Mr. Peter Stegagno
Elekta, Inc.
4775 Peachtree Industrial Boulevard
Building 300, Suite 300
NORCROSS GA 30092

Re: K032996
Trade/Device Name: Elekta Synergy™ System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 IYE
Dated: September 12, 2003
Received: September 25, 2003

Dear Mr. Stegagno:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K032996

Device Name..... Elekta Synergy™ System

Indication for Use:

The Elekta Synergy™ System is intended to be used for radiation therapy treatment of malignant neoplastic diseases, as determined by a licensed medical practitioner.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K032996

(Optional Format 1-2-96)